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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. _____

To direct the Secretary of Health and Human Services to evaluate the extent to which the substitution of interchangeable biological products may be impeded by differences between the system for determining a biological product to be interchangeable and the system for assigning therapeutic equivalence ratings to drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mrs. MILLER-MEEKS introduced the following bill; which was referred to the Committee on _____

A BILL

To direct the Secretary of Health and Human Services to evaluate the extent to which the substitution of interchangeable biological products may be impeded by differences between the system for determining a biological product to be interchangeable and the system for assigning therapeutic equivalence ratings to drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Biologics Competition Act of 2022''.

SEC. 2. STUDY ON CERTAIN IMPEDIMENTS TO THE SUBSTITUTION OF INTERCHANGEABLE BIOLOGICAL PRODUCTS.

Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) complete a study to evaluate the extent to which the substitution of interchangeable biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) may be impeded by differences between the system for determining a biological product to be interchangeable under section 351(k)(4) of such Act (42 U.S.C. 262(k)(4)) and the system for assigning therapeutic equivalence ratings to drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(2) submit a report to the Congress on the results of the study under paragraph (1); and

(3) update the list published under section 351(k)(9)(A) of the Public Health Service Act (42 U.S.C. 262(k)(9)(A)) (commonly referred to as the ''Purple Book'') to implement such changes as the

Secretary deems necessary to harmonize the approach for communicating the substitutability of interchangeable biological products with the approach for communicating therapeutic equivalence ratings assigned to drugs, with the goals of—

(A) minimizing impediments to the substitution of interchangeable biological products; and

(B) maintaining the distinct pathways by which biological products are licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) and drugs are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).